



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,783	02/05/2004	Michael P. Bevilacqua	2331/124	3541
2101	7590	06/15/2006	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			SKOWRONEK, KARLHEINZ R	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/772,783	Applicant(s) BEVILACQUA ET AL.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 Feb 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-66 are pending.

It is noted that use of "according to" in reference to claim dependency is vague and unclear. The occurrence of the phrase "according to" in the preamble of a claim is being interpreted to indicate dependence from the indicated claim, whereas when the "according to" phrase occurs in the body of it is interpreted as NOT indicative of dependence.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, 28-29, 31-32, 34, 36, 38-40, 43, 45, 47, 48, 51, 53, 55-56, 58, and 61 are drawn to descriptive records, classified in class 707, subclass 100.
- II. Claims 27, 30, 33, 35, 37, 39, 41-42, 44, 46, 48, 50, 52, 54, 57, 59-60, 62-63, 65, and 66 are drawn to methods, classified in class 128, subclass 898. Additionally, the inventions of group II are divided into sub-groups.

The inventions are independent or distinct, each from the other because:

Inventions of groups I and II are directed to related information. The related inventions are distinct if the inventions as claimed do not overlap in scope; the inventions as claimed are not obvious variants; and the inventions as claimed are either

Art Unit: 1631

not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the invention of group I, drawn to a descriptive record, is not an obvious variant of and has a materially different design and function from the invention of group II, drawn to a method.

If applicant elects group II, the one of the following must also be elected.

- II.a. Claim 27, drawn to a method of diagnosis, classified in class 128, subclass 898.
- II.b. Claim 30, drawn to method of monitoring change, classified in class 128, subclass 898.
- II.c. Claims 33, 35, 37, 39, 41-42, 50, 52, 54, and 57, drawn to a method establishing a record of an agent, classified in class 128, subclass 898.
- II.d. Claims 44, 46, 48, 59, 60, 62-63, and 65-66, drawn to methods of using a library, classified in class 128, subclass 898.

The inventions are independent or distinct, each from the other because:

Inventions of subgroups II.a - II.d are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, for example, the invention of group II.a, drawn to method of diagnosis, are distinct from the invention of group II.c, drawn to a method of establishing a record of an agent, because a method

Art Unit: 1631

of diagnosis would have materially different design, mode of operation and effect.

Further, the methods of groups II. a to II.d are not obvious variants of each other.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species Requirement

This application contains claims directed to the following patentably distinct species:

- a.) specific records that comprise measurement conditions that are reproducible within 20 percent as recited by claim 1; or
- b.) specific records that comprise gene expression values with coefficients of variation that are less than 3 percent as recited by claim 3.

The election invention of group I additionally requires the election of a single specie from either a or b. .If specie b. is elected, a further election of species is required.

The species are independent or distinct because conditions under which measurements are obtained have a different nature from measured values.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a).

Specie b is subject to a further election of species requirement.

This application contains claims directed to the following patentably distinct species:

- b.1) A single specific number of genes in a panel (up to 100, 3 to 100, 100 to 500, 3, 4, 6, or 12) as recited by claims 7-13, respectively;

- b.2) A single specific sampling circumstance (time of sampling, site of sampling or biological condition) as recited by claim 16;
- b.3) A single specific type of biological molecule (protein or mRNA) as recited by claims 18 and 19;
- b.4) A single specific origin of first and second cell populations (any two populations of cells, same, different, indicator cells from a subject, in a subject or from a subject) as recited by claims 20-24, respectively;
- b.5) A ratio as recited by claim 25;
- b.6) A specific grouping as recited by claim 26;
- b.7) A specific capacity to induce first condition as recited by claim 32;
- b.8) A reversal of adverse effects as recited by claim 56.

Applicant is directed to elect a single specie from each of b.1 to b.4 and elect a single specie from either b.5, b.6, b.7, or b.8. If applicant elects species b.7 or b.8 a further election of species is required.

The species are independent or distinct because all the species have differing natures or are unrelated, for example, the specie b1, directed to a distinct number of genes, are unrelated to the species b.3, directed a specific chemical structure, or b.6, directed to manner of organization.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3-6, 14-15, 17, 28-29, and 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

If species b.7 is elected a further election of species is required.

This application contains claims directed to the following patentably distinct species:

- b.7.i) A single specific agent (nutraceutical, pharmaceutical, infectious, complex mixture) as recited by claims 14, 16, 18, or 40, respectively;
- b.7.ii) A single specific characteristic of an agent (activity or mechanism) as recited by claims 43 or 45, respectively;
- b.7.iii) A single specific interaction (synergistic, interfering, or neutral) as recited by claims 49 and 51;
- b.7.iv) A single specific number compounds (two compounds or multiple compounds) as recited by claims 49 and 51, respectively;

b.7.v) A single specific induced condition (toxic or therapeutic) as recited by claims 53 and 55, respectively.

Applicant is directed to elect a single specie from each of b.7.i to b.7.v.

The species are independent or distinct because each of the species have different natures, for example, species b.7.i, drawn to chemicals, have a different nature from the species of b.7.iii, drawn to types of interactions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3-6, 14-15, 17, and 32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

If applicant elects species b.8 the following election of species is required.

This application contains claims directed to the following patentably distinct species:

b.8.i) A single causative agent (infectious, biological warfare, or environmental) as recited by claim 56.

The species are independent or distinct because the species have different intended uses. For example, an infectious agent could be naturally occurring or be used therapeutically such as in gene therapy whereas a biological warfare agent is by definition designed to incapacitate a human opponent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3-6, 14-15, 17, and 56 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a).

If applicant elects group II.c the following election of Species is required.

This application contains claims directed to the following patentably distinct species:

- 1.) A single specific causative agent (nutraceutical, pharmaceutical, infectious or complex mixture) as recited by claims 35, 37, 39, or 41, respectively, or (infectious, biological warfare, or environmental) as recited by claim 57;
- 2.) A single specific mixture (complex mixture, two compound mixture, or multiple compound mixture) as recited by claims 42, 50, or 52, respectively;
- 3.) A single specific interaction type (synergistic, additive, negative, neutral, or toxic) as recited by claims 42, 50, and 52.

Applicant is directed to elect a single specie from each of 1, 2, and 3.

The species are independent or distinct because, for example, the agents of specie 1, distinct chemical structures, are unrelated to the interaction types of specie 3 or the compositions of specie 2.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is positioned below the printed name and title.